

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order which the corresponding issues were raised in the Office Action.

**I. Rejections under 35 U.S.C. §112, Second Paragraph**

Claims 5, 6, 11, and 14-18 are rejected under 35 U.S.C. §112, Second Paragraph for indefiniteness.

Specifically, the Examiner rejects claim 5 alleging that it is unclear what further structure [error: should have been "step"] is being claimed therein. The Examiner's allegation is completely groundless. Claim 5 positively recites a step of placing the energy delivery surface of an RF electrode on the skin surface. This step limits the scope of independent claim 1 that recites the step of placing the energy delivery surface of an energy source on the skin surface. Applicants submit that claim 5 further narrows the scope of independent claim 1 and is sufficient definite under 35 U.S.C. §112, Second Paragraph. Withdrawal of this ground of rejection is respectfully requested.

The Examiner also rejects claim 14 alleging that it is unclear what further method step is being claimed therein. The Examiner's allegation is completely groundless. Claim 14 positively recites a step of creating a reverse thermal gradient by providing a cooling medium to cool the skin surface. Applicants submit that claim 14 further narrows the scope of independent claim 1 and is sufficient definite under 35 U.S.C. §112, Second Paragraph. Withdrawal of this ground of rejection is respectfully requested.

The Examiner also rejects 11 and 15-18 for lacking antecedent basis as to the term "the loose skin surface". Applicants amend claims 11-12 and 15-18 to cure these editorial defects. Withdrawal of the rejection is therefore respectfully requested.

**II. Rejections under 35 U.S.C. §112, First Paragraph**

Claims 19-21, 55, and 56 are rejected under 35 U.S.C. §112, First Paragraph for insufficient written description. Specifically, the Examiner alleges that the specification does not disclose how to control the temperature or how to enablingly sense the temperature of the underlying tissue. Applicants traverse the Examiner's grounds of rejection under 35 U.S.C. §112, First Paragraph.



Applicants respectfully direct the Examiner's attention to the section starting from page 13, line 2 to page 15, line 16, and figures 4-6 which provide detailed guidance as to how to control the temperature and impedance of the skin by using a sensor and feedback control mechanism. Applicants submit that in view of the description and block diagrams illustrated in Figures 5 and 6 one of ordinary skill in the art would be understand how to control the temperature of the underlying collagen containing tissue. Thus, claims 19-21, 55, and 56 are sufficiently definite. Withdrawal of the rejection is therefore respectfully requested.

### III. Rejections under 35 U.S.C. §103

The Examiner rejects claims 1, 4, 5, 11-21 and 53-60 under 35 U.S.C. §103 (a) as being unpatentable over Sand (US Patent No: 4,976,709) in combination with Storm III (US Patent No: 4,140,130). The Examiner also rejects claim 6 under 35 U.S.C. §103 (a) as being unpatentable over Sand in combination with Storm III and further in view of Lax et al. (US Patent No: 5,569,242)

Independent claim 1 as amended specifies a method for treating wrinkled skin. According to the method, the energy delivery surface of an energy source (e.g., an RF electrode) is positioned on the surface of the wrinkled skin and in conjunction with the creation of reverse thermal gradient on the skin sufficient energy is delivered to reduce the depth of the wrinkle.

In contrast, Sand teaches a method for reshaping cornea by directly irradiating the cornea using laser. See "Summary of the Invention", column 4, line 23-31. There is neither teaching nor suggestion of the claimed step of compressing the template by an external mechanical force in conjunction with the delivery of energy so as to treat wrinkles of the skin.

The secondary reference, Storm III, fails to supply these requisite elements missing in Sand. Storm III teaches a method of treating tumors by using hyperthermia, which is completely irrelevant to the claimed method of treating wrinkles of the skin by delivering energy and applying external mechanical force to modify collagen matrix in the skin and subcutaneous soft tissue in order to achieve esthetic effects. To the contrary, Storm III teaches heating the tumor-bearing or deep musculo-skeletal tissue while "maintaining the skin and subcutaneous tissue therebeneath in a suitably relatively cooled state". Column 2, lines 39-43. Thus, Storm III not only fails to suggest the claimed method but also effectively teaches away from the present invention.

*not relevant to U1*



It is a well-established tenet of patent law that when an obviousness rejection is based upon the teachings of a combination of references, there must be something in the art as a whole to suggest the desirability of making the combination. Grain Processing v. American Maize 5 USPQ2d 1788, 1792 (Fed. Cir. 1988). As the Federal Circuit has cautioned on several occasions, when prior art references are based upon a selective combination of elements from more than one reference, there must be some reason for the combination other than the hindsight gleaned from the claimed invention itself. Interconnect Planning Corp. v. Feil 774 F2d 1132, 1143 (Fed. Cir. 1985).

Applicants respectfully submit that the Examiner impermissibly has based the present rejection upon hindsight. There is nothing in the cited references which would suggest the claimed method for treating wrinkles of the skin. The disclosure of laser sight correction in Sand does not provide a suggestion that a sufficient amount of energy should be delivered in conjunction with the creation of reverse thermal gradient through an energy delivery device incorporated into the template to reduce the depth of a wrinkle. Since the Examiner has failed to show any motivation to provide the method as claimed, the Examiner has failed to set forth a *prima facie* case for obviousness. Withdrawal of this ground of rejection is respectfully requested.

#### CONCLUSION

In light of the Amendments and the arguments set forth above, Applicants earnestly believe that they are entitled to a letters patent, and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

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Date: July 24, 2001

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Title:**

Please amend the title as follows:

[METHOD AND APPARATUS FOR CONTROLLED CONTRACTION OF COLLAGEN TISSUE] METHOD FOR SMOOTHING WRINKLED SKIN BY CONTROLLED CONTRACTION OF COLLAGEN TISSUE BENEATH THE SKIN SURFACE

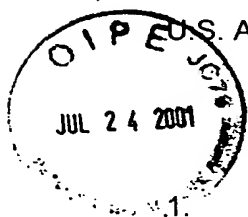
**In the Claims:**

Please amend the claims as follows:

11. (Amended) The method of claim 1, wherein delivery <sup>my</sup> energy includes delivering a sufficient amount of microwave energy to [tighten] smoothing the [loose] wrinkled skin surface.
12. (Amended) The method of claim 1, wherein delivery <sup>my</sup> energy includes delivering a sufficient amount of ultrasound energy to [tighten] smoothing the [loose] wrinkled skin surface.
15. (Amended) The method of claim 1, wherein treating a [loose] wrinkled skin surface overlying a collagen containing tissue site includes contracting a portion of the collagen containing tissue site that is in a subdermal layer.
16. (Amended) The method of claim 1, wherein treating a [loose] wrinkled skin surface overlying a collagen containing tissue site includes contracting a portion of the collagen containing tissue site that is in a deep dermal layer.
17. (Amended) The method of claim 1, wherein treating a [loose] wrinkled skin surface overlying a collagen containing tissue site includes contracting a portion of the collagen containing tissue site that is in a subcutaneous dermal layer.

18. (Amended) The method of claim 1, wherein treating a [loose] wrinkled skin surface overlying a collagen containing tissue site includes contracting a portion of the collagen containing tissue site that is facial and muscle tissue.

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PENDING CLAIMS

1. A method of treating a skin surface with a wrinkle, the skin surface overlying a collagen containing tissue, comprising:

identifying a person having a skin surface with a wrinkle;  
providing an energy source with an energy delivery surface;  
positioning the energy delivery surface in contact with the skin surface;  
producing energy from the energy source;  
creating a reverse thermal gradient, wherein a temperature of the skin surface is less than a temperature of the collagen containing tissue; and  
delivering energy through the skin surface to the collagen containing tissue and contract at least a portion of the collagen containing tissue with controlled cell necrosis, such that the depth of the wrinkle is reduced.

4. The method of claim 1, wherein delivering energy includes delivering RF energy from the energy source that is an RF energy source.

5. The method of claim 4, wherein positioning the energy delivery surface includes positioning an energy delivery surface of an RF electrode on the skin surface.

6. The method of claim 5, further comprising:  
applying electrolytic media to the wrinkled skin from a source of electrolytic media coupled to the RF electrode.

11. The method of claim 1, wherein delivery<sup>ing</sup> energy includes delivering a sufficient amount of microwave energy to smoothing~~ing~~ the wrinkled skin surface.

12. The method of claim 1, wherein delivery<sup>ing</sup> energy includes delivering a sufficient amount of ultrasound energy to smoothing~~ing~~ the wrinkled skin surface.

13. The method of claim 1, wherein delivering energy includes delivering a sufficient amount energy through the skin surface to partially denature the collagen containing tissue site by cleaving heat labile cross-links of collagen molecules.

14. The method of claim 1, wherein creating a reverse thermal gradient includes providing a cooling medium to cool the skin surface.
15. The method of claim 1, wherein treating a wrinkled skin surface overlying a collagen containing tissue site includes contracting a portion of the collagen containing tissue site that is in a subdermal layer.
16. The method of claim 1, wherein treating a wrinkled skin surface overlying a collagen containing tissue site includes contracting a portion of the collagen containing tissue site that is in a deep dermal layer.
17. The method of claim 1, wherein treating a wrinkled skin surface overlying a collagen containing tissue site includes contracting a portion of the collagen containing tissue site that is in a subcutaneous dermal layer.
18. The method of claim 1, wherein treating a wrinkled skin surface overlying a collagen containing tissue site includes contracting a portion of the collagen containing tissue site that is facial and muscle tissue.
19. The method of claim 1, wherein delivery energy includes delivering sufficient amount of energy such that the average temperature of the collagen containing tissue does not exceed 80 degrees C.
20. The method of claim 1, wherein delivery energy includes delivering sufficient amount of energy such that the average temperature of the collagen containing tissue does not exceed 75 degrees C.
21. The method of claim 1, wherein delivery energy includes delivering sufficient amount of energy such that the average temperature of the collagen containing tissue does not exceed 70 degrees C.

53. The method of claim 1, further comprising:  
sensing a temperature of the skin surface during delivery of the energy through the skin surface.
54. The method of claim 1, further comprising:  
sensing a temperature of the skin surface after delivery of the energy through the skin surface.
55. The method of claim 1, further comprising:  
sensing a temperature of a tissue underlying the skin surface during the delivery of the energy through the skin surface.
56. The method of claim 1, further comprising:  
sensing a temperature of a tissue underlying the skin surface after delivery of the energy through the skin surface.
57. The method of claim 1, further comprising:  
sensing an impedance of the skin surface during delivery of the energy through the skin surface.
58. The method of claim 1, further comprising:  
sensing an impedance of the skin surface after delivery of the energy through the skin surface.
59. The method of claim 1, further comprising:  
sensing an impedance of a tissue underlying the skin surface during the delivery of the energy through the skin surface.
60. The method of claim 1, further comprising:  
sensing an impedance of a tissue underlying the skin surface after the delivery of the energy through the skin surface.